

**REMARKS**

Claims 21-41 were pending in the application. Claims 21, 25, 32, 34, and 41 have been amended. The amendments are supported fully by the claims and/or specification as originally filed and, thus, do not represent new subject matter. Upon entry of these amendments, Claims 21-41 will be pending and under active consideration. Claims 21, 32, 34, and 41 are independent.

Claim 21 has been amended to recite that the resistant starch polyglucane is produced by the action of amylosucrase acting on sucrose, wherein the degree of branching in the 2, 3 or 6 position is 0%, the degree of crystallinity of the resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous. The amendment is supported fully by the claims and/or specification as originally filed and, thus, does not represent new subject matter. In particular, support for the recitation of the product by process recitation of the production of resistant starch polyglucane by the action of amylosucrase acting on sucrose may be found in the specification as filed at the last paragraph bridging page 6-7. Support for the recitation of wherein the degree of branching in the 2, 3 or 6 position is 0% is found at page 5, lines 6-8 of the English translation of the specification as filed. Support for the recitation of the degree of crystallinity of the resistant starch being greater than 65% is based upon the inherent crystallinity of the resistant starch prepared according to Claim 21. Support for the recitation of wherein the resistant starch contains no phosphorous is based upon the fact that the resistant starch prepared according to Claim 21 contains absolutely no

phosphorous. Claims 32, 34, and 41 are amended to conform to Claim 21, as amended.

If deemed required by the Examiner, Applicants would be willing to provide experimental data in the form of a Declaration Under 37 C.F.R. Section 1.132 to provide evidence that the degree of crystallinity of the resistant starch is greater than 65% and that the resistant starch contains no phosphorous.

Claim 25 has been amended to recite that the mean diameter of the microparticles is 1 nm to 100  $\mu$ m. Support for the amendment may be found in the specification as filed on page 10, lines 34-36 of the English translation.

Applicants respectfully request entry of the amendments and remarks made herein into the file history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action are respectfully requested.

**I. The Rejection Under 35 U.S.C. § 102(b) Should Be Withdrawn**

**A The Rejection Over Henley *et al.* (U.S. Patent No. 5,409,542) Under 35 U.S.C. § 102(b) Should Be Withdrawn**

The Office Action at pages 3-5 rejects Claims 21, 27-36, and 39-41 under 35 U.S.C. 102(b) as being allegedly anticipated by Henley *et al.* (U.S. Patent No. 5,409,542)(hereinafter, "Henley") for the reasons of record. In particular, the Office Action alleges Henley describes the production of a resistant starch from linear  $\alpha$ -1,4 glucan, said linear glucan being prepared by debranching starch. The Office Action alleges that Henley discloses that the glucan does not contain any branch points. The

Office Action indicates that Henley describes the linear  $\alpha$ -1,4 glucan product recited in applicant's claims, allegedly clearly meeting the limitation requiring less than 0.5% branch points.

The Office Action further alleges that Henley also describes that the linear  $\alpha$ -1,4 glucans prepared by debranching are useful as a fiber source when combined with foods. The Office Action further alleges that although the unbranched amylose products are not prepared using amylosucrase, they are allegedly indistinguishable therefrom, since the amylosucrase-polymerized products have an identical chemical structure to the enzymatically debranched products. Applicants traverse respectfully.

Applicants submit respectfully that Henley does not anticipate the rejected claims, as amended, because Henley does not disclose each and every element of the claimed subject matter as required for a *prima facie* showing of anticipation. In particular, the claimed subject matter is directed to resistant starch obtained from a water-insoluble linear  $\alpha$ -1,4-D-glucan produced by the action of amylosucrase acting on sucrose, wherein the degree of branching in the 2, 3 or 6 position is 0%, the degree of crystallinity of the resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous.

Without acquiescing in the allegation that Henley teaches a linear  $\alpha$ -1,4-D-glucan that does not contain any branch points, Applicants submit respectfully that Henley does not teach or suggest the production or use of resistant starches wherein the degree of branching in the 2, 3 or 6 position is 0%, the degree of crystallinity of the

resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous.

Applicants respectfully submit that there are three main differences between debranched native starches of the prior art and the poly-glucanes of the present invention made by the enzymatic activity of Amylosucrase acting on sucrose.

a) Phosphorylation: Applicants respectfully submit that native starches are always phosphorylated. See the attached document "Morphology and composition of starch", T. Galliard and P. Bowler, in: Starch: Properties and Potential, T. Galliard (Ed.) Society of Chemical Industry, John Wiley & Sons, 1987, especially chapter 3.2. Applicants respectfully submit that it becomes clear, that starches always contain phosphorous (besides other contaminants), and debranching does not change that fact. The poly-glucanes of the present invention do not contain phosphorous, either in the form of lipids or in the form of phosphoesters, etc.

b) Crystallinity: Applicants respectfully submit that experiments of the applicant have shown that the crystallinity of resistant starch made from the polyglucane of the present invention is over 65%, whereas the crystallinity of e.g. Novelose 330 as tested was shown to be only 30-40%.

c) Linearity: Applicants respectfully submit that the polyglucanes of the present invention are absolutely linear. No branching points whatsoever could be detected using the most accurate method currently available, i.e. GCMS-analysis. In debranched starches, branching points were, however, always detectable, which means that debranching was not complete, despite assertions to the contrary in the prior art.

Applicants respectfully submit that, based upon these three characteristics alone, it is evident that a polyglucane made by the enzymatic action of amylosucrase acting on sucrose is indeed novel over the debranched starches of the prior art.

If deemed necessary by the Examiner, Applicants would be more than willing to provide experimental data in the form of a Declaration Under 37 C.F.R. Section 1.132 to support the assertions provided above.

As acknowledged by the Office Action, Henley teaches at most only that the enzymatic treatment is permitted to continue until essentially complete debranching has occurred. Thus, the limitations of wherein the degree of branching in the 2, 3 or 6 position is 0%, the degree of crystallinity of the resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous are not disclosed in Henley as is required for a *prima facie* showing of anticipation. Accordingly, Claims 21, 27-36 are not anticipated by Henley.

Likewise, Applicants submit respectfully that Claims 39, 40 and the method of Claim 41 are also not anticipated by Henley. Claims 39 and 40 incorporate the limitations of Claim 34, namely, resistant starches wherein the degree of branching in the 2, 3 or 6 position is 0%, the degree of crystallinity of the resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous. Because the limitations of wherein the degree of branching in the 2, 3 or 6 position is 0%, the degree of crystallinity of the resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous are not disclosed in Henley as is required for a *prima facie* showing of anticipation, Claims 39-41 are also not anticipated by Henley.

In view of the above, Applicants submit respectfully that Claims 21, 27-36, and 39-41 are not anticipated by the Reference. Accordingly, Applicants request respectfully that the rejection of Claims 21, 27-36, and 39-41 under 35 U.S.C. § 102(b) be withdrawn.

**B. The Rejection Over Zallie *et al.* (U.S. Patent No. 5,480,669) Under 35 U.S.C. § 102(b) Should Be Withdrawn**

The Office Action at pages 5-6 rejects Claims 21, 22, 24, 26, 30-36, and 39-41 under 35 U.S.C. 102(b) as being allegedly anticipated by Zallie *et al.* (U.S. Patent No. 5,480,669)(hereinafter, "Zallie") for the reasons of record. In particular, the Office Action alleges that Zallie describes the production of a resistant starch from linear  $\alpha$ -1,4 glucan, said linear glucan being prepared by debranching starch. The Office Action alleges that Zallie discloses that the glucan does not contain any branch points. The Office Action further alleges that Zallie also describes that the linear  $\alpha$ -1,4 glucans prepared by debranching are useful as a fiber source when combined with extruded foods including pasta. Moreover, the Office Action alleges further that, because the mixing of the resistant starch and other ingredients will inherently result in "enrobing" of some of the compounds present, claims directed to this embodiment must be considered to be anticipated as well. Finally, the Office Action alleges that, although the unbranched amylose products are not prepared using amylosucrase, they are allegedly indistinguishable therefrom, since the amylosucrase-polymerized products have an identical chemical structure to the enzymatically debranched products. Applicants traverse respectfully.

Applicants submit respectfully that Zallie does not anticipate the rejected claims, as amended, because Zallie does not disclose each and every element of the claimed subject matter as required for a *prima facie* showing of anticipation. In particular, the claimed subject matter is directed to resistant starch obtained from a water-insoluble linear  $\alpha$ -1,4-D-glucan produced by the action of amylsucrase acting on sucrose, the degree of branching in the 2, 3 or 6 position is 0%, the degree of crystallinity of the resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous.

Without acquiescing in the allegation that Zallie teaches a linear  $\alpha$ -1,4-D-glucan that does not contain any branch points, Applicants submit respectfully that Zallie does not teach or suggest the production or use of resistant starches wherein the degree of branching in the 2, 3 or 6 position is 0%, the degree of crystallinity of the resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous. Indeed, as acknowledged by the Office Action, Zallie teaches at most only that the enzymatic treatment is permitted to continue until essentially complete debranching has occurred. Thus, the limitations of wherein the degree of branching in the 2, 3 or 6 position is 0%, the degree of crystallinity of the resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous are not disclosed in Zallie as is required for a *prima facie* showing of anticipation. Accordingly, Claims 21, 22, 24, 26, 30-36 are not anticipated by Zallie.

Likewise, Applicants submit respectfully that Claims 39, 40 and the method of Claim 41 are also not anticipated by Zallie. Claims 39 and 40 incorporate the limitations of Claim 34, namely, resistant starches wherein the degree of branching in the 2, 3 or 6

position is 0%, the degree of crystallinity of the resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous. Because the limitations of wherein the degree of branching in the 2, 3 or 6 position is 0%, the degree of crystallinity of the resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous are not disclosed in Zallie as is required for a *prima facie* showing of anticipation, Claims 39-41 are also not anticipated by Zallie.

In view of the above, Applicants submit respectfully that Claims 21, 22, 24, 26, 30-36, and 39-41 are not anticipated by the Reference. Accordingly, Applicants request respectfully that the rejection of Claims 21, 22, 24, 26, 30-36, and 39-41 under 35 U.S.C. § 102(b) be withdrawn.

**II. The Rejections Under 35 U.S.C. § 103(a) Should Be Withdrawn**

**A. The Rejection Over Henley *et al* (U.S. Pat. 5,409,542) and Zallie *et al* (U.S. Pat. 5,480,669) in view of Brown (WO 96/08261)**

The Office Action, at pages 5-8, rejects Claims 21-41 under 35 U.S.C. § 103(a) as being allegedly obvious over Henley *et al* (U.S. Pat. 5,409,542) and Zallie *et al* (U.S. Pat. 5,480,669) in view of Brown (WO 96/08261). The Office Action alleges that Henley/Zallie describe the production of resistance starch from linear "-1,4 glucans, and the use of the resistant starch in foods. The Office Action acknowledges that Henley/Zallie differ from the claims in that they do not disclose the use of the glucan as a carrier combined with a beneficial agent is bifidobacteria, as recited in claims 23 and 38. However, the Office Action alleges that Brown discloses a pharmaceutical



composition beneficial to the gastrointestinal tract, said composition comprising resistant starch and bifidobacteria. Brown also discloses that starches containing over 80% amylose (i.e., over 80% linear  $\alpha$ -1,4 glucan) are preferred. Thus, the Office Action alleges that the artisan of ordinary skill, recognizing from Henley/Zallie resistant starch obtained from unbranched  $\alpha$ -1,4 glucans are suitable for use as carriers for beneficial agents, clearly would have been motivated to have used Henley/Zallie's resistant starch as carriers for Brown's bifidobacteria, and that the specific motivation would have been derived from Brown's disclosure of the desirability of combining the bifidobacteria with high amylose starch, the artisan of ordinary skill clearly recognizing that Henley/Zallie's glucans were in fact identical to pure amylose, and therefore well within the at least 80% amylose disclosed by Brown as being desirably combined with the bifidobacteria. Applicants traverse respectfully.

As explained above, Applicants submit respectfully that each of the primary references of Henley/Zallie, either alone or in combination, do not teach or suggest the production or use of resistant starches wherein the degree of branching in the 2, 3 or 6 position is 0%, the degree of crystallinity of the resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous. This fundamental deficiency is not cured by reference to the secondary reference of Brown. Therefore, without acquiescing in the allegation that one skilled in the art would have been specifically motivated to combine bifidobacteria with high amylose starch, Applicants submit respectfully that the burden of presenting a *prima facie* showing of obviousness under 35 U.S.C. § 103(a) has not been met.

Accordingly, Applicants submit respectfully that the rejection of Claims 21-41 under 35 U.S.C. § 103(a) has been overcome, and Applicants request respectfully that the rejection of Claims 21-41 under 35 U.S.C. § 103(a) be withdrawn.

**B. The Rejection Over Kossman *et al.* (WO 95/31553) in view of Henley *et al* (U.S. Pat. 5,409,542) and Zallie *et al* (U.S. Pat. 5,480,669) and further in view of Brown (WO 96/08261)**

The Office Action, at pages 8-9, rejects Claims 21-41 as being allegedly unpatentable over Kossman *et al* (WO 95/31553) in view of Henley *et al* (U.S. Pat. 5,409,542) and Zallie *et al* (U.S. Pat. 5,480,669), and in further view of Brown (WO 96/08261) under 35 U.S.C. 103(a) for the reasons of record. In sum, the Office Action alleges that Kossman differs from the claims in that Kossman does not explicitly disclose the use of the glucan in the production of resistant starch. The Office Action alleges that each of Henley/Zallie discloses that linear "-1,4 glucans such as amylose are suitable for the production of resistant starch. Thus, the Office Action alleges that even if the artisan of ordinary skill were to consider the resistant starches of Henley/Zallie to be different from the starches recited in applicant's claims because the Henley/Zallie starches were produced by debranching rather than the polymerization reaction of Kossman, the artisan of ordinary skill viewing Kossman in light of Henley/Zallie clearly would have been allegedly motivated to have produced resistant starch from the linear amylosucrase-polymerized glucans disclosed in Kossman. The Office Action further alleges that in view of the fact that Brown directly discloses the

suitability of resistant starches as carriers for bifidobacteria, the use thereof is allegedly considered obvious. Applicants traverse respectfully.

Applicants respectfully submit that Kossman does not teach or suggest the use of resistant starches as claimed by Applicants. Neither Kossman nor the secondary references of Henley/Zallie, either alone or in combination, teach or suggest the production or use of resistant starches wherein the degree of branching in the 2, 3 or 6 position is 0%, the degree of crystallinity of the resistant starch is greater than 65%, and wherein the resistant starch contains no phosphorous. This fundamental deficiency is not cured by reference to the remaining secondary reference of Brown. Therefore, without acquiescing in the allegation that Brown cures the deficiency in Kossman relating to the use of the glucan as a carrier when the beneficial agent is bifidobacteria, or that Brown discloses a pharmaceutical composition beneficial to the gastrointestinal tract, said composition comprising high amylose starch and bifidobacteria as now claimed by Applicants, Applicants submit respectfully that the burden of presenting a *prima facie* showing of obviousness under 35 U.S.C. § 103(a) has not been met.

In view of the above, Applicants request respectfully that the 35 U.S.C. § 103(a) rejection of Claims 21-41 be withdrawn.

### **III. The Rejections Under 35 U.S.C. § 112, Second Paragraph**

At pages 2-3 of the Office Action, Claim 25 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to point out particularly and claim distinctly the subject matter regarded as the invention. The Office Action

alleges that, in Claim 22, the recitation “microparticles” is unclear. Applicants traverse respectfully.

Applicants once again respectfully direct Examiner’s attention to page 10, lines 21-36, of the specification as filed which provide Applicants’ definition of the term “microparticles.” Applicants respectfully submit that the meanings of the rejected terms are clear and unambiguous in light of the teachings found in the specification as filed. Nevertheless, without acquiescing in the propriety of the rejection and solely to advance prosecution, Applicants have amended Claim 25 to now recite microparticles with a mean diameter of 1 nm to 100  $\mu$ m. Support for the amendment may be found in the specification as filed on page 10, lines 34-36 of the English translation. In view of the amendment to Claim 25, Applicants respectfully submit that the Claim 25 is more than adequately defined to meet the requirements of 35 U.S.C. § 112, second paragraph.

Accordingly, Applicants request respectfully that the rejection of Claim 25 under 35 U.S.C. § 112, second paragraph, be withdrawn.

**CONCLUSION**

Applicants submit respectfully that the present application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

**AUTHORIZATION**

Applicants believe there is no fee due in connection with this filing. However, to the extent required, the Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Gilberto M. Villacorta", with a stylized flourish at the end.

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